Serial No. 10/718,236

Filing Date: November 19, 2003

Title: MINIMALLY INVASIVE VALVE REPAIR PROCEDURE AND APPARATUS

### Remarks

This is responsive to the Final Office Action mailed April 1, 2008 and in support of the concurrently-filed Request for Continued Examination. In that Office Action, Claims 17, 19, 20, and 22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Northrup, U.S. Patent No. 5,972,024 ("Northrup") in view of Pyka et. al., U.S. Patent No. 5,002,563 ("Pyka") and further in view of Krajicek, U.S. Patent No. 5,413,597 ("Krajicek").

The Examiner's indication that claims 18, 21, 24, and 25 have been allowed is noted with appreciation. The Examiner's indication that claim 23, although objected to, would be deemed allowable if rewritten in independent form, is also noted with appreciation.

With this Response, claims 17 and 20 have been amended. Claims 26-29 have been added. Newly added claims 27 and 29 depend from allowable claims 18 and 21 respectively are believed to be allowable at least by reason of their dependency from allowable claims. The amendments to the claims are fully supported by the specification as filed. No new matter has been added by way of these amendments. Support for these amendments can be found throughout the Specification and particularly at Page 8 lines 20-25.

Thus, claims 17-29 are pending in the application and are presented for reconsideration and allowance.

### **Interview Summary**

Applicants wish to thank the Examiner for courtesies extended during the Examiner Interview held on May 22, 2008 between the Examiner and the undersigned. During the Interview the rejected independent claims as well as Fig. 9 of Northrup U.S. Patent 5,972,024 were discussed. No agreement was reached.

## Claim Rejections Under 35 U.S.C. §103(a)

In the §103(a) rejection of independent claims 17 and 20, the Examiner alleges that Northrup discloses the invention substantially as claimed in that Northrup discloses

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in Figures 4-9 and col. 4, lines 5-54 a clip assembly and a method of holding two tissue parts together where the assembly and method include two clips (60) ... two tissue penetrating needles (40) and a flexible connector (e.g. 310 in Fig. 9) connecting the other end points of the two clips together; where the method includes penetrating and completely pulling one of the needles through a tissue part (e.g. 320 in Fig. 9) and penetrating an completely pulling the other of the needles through an adjacent tissue part (e.g. also at 320) while the clips are each in an open configuration and pulling the needles until each of the clips is hooked to a corresponding one of the tissue parts and where the two tissue parts are held together by the flexible connector stretched between the clips.

# Independent Claim 17

As set out above, the Examiner is contending that elements 60 are the clips while elements 40 are the penetrating needles. Applicants' claim 17 provides in part, "two tissue penetrating needles each *connected to one of said two end points* of a corresponding one of said two clips through a flexible member and a flexible connector *connecting the other end points* of said two clips together. First, Applicants respectfully submit that the Examiner has failed to articulate where in Northrup one end of clip 60 is connected to a needle through a flexible member while the other end of clip 60 is connected through a flexible connector to another clip 60. Nor does the Examiner allege that it would be obvious in light of Northrup or any of the cited references to provide such a device. The Examiner contends only that element 310 is the flexible connector and that this "flexible connector" connects "the other end points" of the two clips together. In other words, there is no suggestion that Northrup discloses a clip connected at both ends to secondary members or elements.

In addition, the Examiner has alleged that element 310 is a flexible connector connecting "the other end points of the two clips together." Applicants respectfully disagree. Elements 310 and 320 of Northrup are the structures to be joined together by way of, for example, the holding device 60 of Northrup. In other words, elements 310 and 320 are the structures to which the device of Northrup is applied and are not part of the device of Northrup.

Serial No. 10/718,236

Filing Date: November 19, 2003

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Furthermore, neither Pyka nor Krajicek serve to remedy the deficiencies of Northrup. Even if the clip of Pyka were to be applied to the device of Northrup, there remains a lack of disclosure of a connection at each end of the clip. Likewise, substituting the vascular prosthesis of Krajicek for Northrup's tissue structure 310, which the Examiner purports to be a flexible connector, would not remedy the lack of two connections, one at each end of the clip.

## Independent Claim 20

The Examiner alleges also that Northrup discloses "the two tissue parts are held together by the flexible connector stretched between the clips." Since the Examiner has alleged that the flexible connector is structure 310 and the two tissue parts as set forth in Applicants' claim are both structure 320, the Examiner is effectively arguing that structure 310 holds structure 320 to structure 320. The Applicants respectfully submit that this runs contrary to logic and to a fair reading of Northrup. As is clearly evident in Fig. 9 of Northrup, it is the holding device 60 of Northrup which is capable of holding structures together and not, as suggested by the Examiner, structure 310.

In addition, neither Pyka nor Krajicek serve to remedy the deficiencies of Northrup. Even if the clip of Pyka were to be applied to the device of Northrup, there remains a lack of disclosure of a flexible connector such that two tissue parts are held together by the flexible connector stretched between the clips. The Examiner alleges that it would have been obvious to apply an artificial flexible connector in view of Krajicek in the apparatus and method of Northrup or Northrup in view of Pyka. Applicants respectfully disagree. Substituting the vascular prosthesis of Krajicek for Northrup's tissue structure 310, which the Examiner purports to be a flexible connector, would not remedy the lack of a means to hold the structures 310 and 320 together. In other words, the vascular prosthesis of Krajicek can no more hold structure 320 of Northrup to another part of structure 320 (recall as discussed herein, the Examiner contends that structure 320 is *both* tissue parts as claimed by Applicants) than element 310 of Northrup can.

Additionally, Applicants have amended claims 17 and 20 to include that the tissue penetrating needles are *releasably* connected to the clips through a flexible member. At

Page 9 Dkt.: P0021779.02

## AMENDMENT AND RESPONSE UNDER 37 C.F.R. §1.111

Serial No. 10/718,236

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least for the reasons presented above and in addition in light of the amendments made, independent claims 17 and 20 and the claims dependent therefrom are allowable over Northrup in view of Pyka and further in view of Krajicek.

# **CONCLUSION**

In view of the above, Applicant respectfully submits that pending claims 17-29 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 17-29 are respectfully requested.

A Request for Continued Examination as well as a petition for a two-month extension of time is being made concurrently with this response via the EFS-web.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-2546.

Respectfully submitted,

Date: September , 2008

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